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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,729	12/21/2001	Jaap M. Middeldorp	9250-13DVCTDV	6359

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EXAMINER	
KIM, YOUNG J	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 12/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,729	MIDDELDORP ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-9,23 and 25-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-9,23 and 25-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 4, 2004 has been entered.

Preliminary Remark

Claims 6-9, 23, and 25-31 are pending and are under prosecution.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-9, 23, and 25-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims encompass nucleic acids which are described for one skilled in the art to recognize that at the time the application was filed, Applicants were in possession of the claimed invention for the following reasons.

Claims involve an isolated nucleic acid that share a single nucleotide in common with SEQ ID NO: 1 or SEQ ID NO: 3 (denoted by the phrase, "a subsequence thereof"), wherein said nucleic acid would encode ***any*** polypeptide that is immunoreactive with ***any*** antibodies to EBV, including specific and non-specific antibodies, such nucleic acid would encompass a wide array of genus of nucleic acids to which the instant application lacks description.

Middeldorp et al. (Journal of Virological Methods, 1988, vol. 21, pages 133-146), while discussing peptides that are reactive with EBV antibodies, state:

"The immunoblot studies reveal an ***enormous diversity*** in EBV-specific polypeptides recognised [*sic*] by different patients, both for IgM and IgG." (page 133).

Where there is such diversity for EBV-***specific*** polypeptides, the claims embrace a genus which encompasses polypeptides that are immunochemically reactive with non-specific antibodies to an EBV.

With regard to an isolated nucleic acid sequence encoding ***any*** peptide that is immunochemically reactive with antibodies (specific and non-specific) to the EBV, comprising at least a single residue in common with VCA-p18 or VCA-p40, such nucleic acids, for the same reasons above, would not be adequately described for a skilled artisan to recognize that applicants had possession of the claimed invention at the time the application was filed.

Additionally, with regard to the embodiment of a nucleic acid encoding, "a functional variant of said peptide," the specification lacks absolute description for this embodiment because

no function has been attributed for the claimed peptide other than said peptide being reactive with ***any*** antibodies to EBV.

Amending the claims to become drawn to a nucleic acid consisting of SEQ ID NO: 1 or 3 would overcome this rejection.

For the above reasons, the invention as claimed lacks a written description for the genus embraced by the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-9, 23, 24, and 25-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Ambinder et al. (Abstracts from Annual Meeting American Society of Microbiology, 1989, 89 Meet., 111, cited previously).

The instant rejection is predicated on the decision from *In re Mott*, 190 U.S.P.Q. 536 (CCPA 1975), wherein the court expressed that, "[c]laims must be given broadest reasonable construction their language will permit in ex parte prosecution, and applicant who uses broad language runs the risk that others may be able to support the same claim with a different disclosure."

For the purpose of claim interpretation, Examiner interprets claim 6 as being is drawn to an isolated nucleic acid sequence encoding a ***peptide***, comprising at ***least part of the VCA-p18 or***

VCA-p40 protein, wherein said peptide is immunochemically reactive with ***antibodies*** to the EPV, or a functional variant of said peptide. The ***underlined***, "at least part of," is given the broadest reasonable interpretation as encompassing a single amino acid residue.

Ambinder et al. disclose a method of detecting EBV sequences in clinical specimen by amplification method involving primers. A plasmid containing EBV is disclosed as being amplified, which evidences the presence of a nucleic acid encoding EBV with at least one common residue with the VCA-p18 or VCA-p40.

Claims 7 and 8 are interpreted as being drawn to a nucleic acid comprising the nucleic acid sequence as shown in SEQ ID NO: 1 (or SEQ ID NO: 3) ***or a subsequent thereof***, wherein said subsequence encodes ***an*** EBV peptide that is immunochemically reactive with antibodies to the EBV.

Hence, any nucleic acid encoding ***an*** EBV peptide, which shares at least a single nucleotide sequence with that of SEQ ID NO: 1 or NO: 3 would meet the claimed limitation based on a broadest reasonable interpretation.

Ambinder et al. disclose a method of detecting EBV sequences in clinical specimen by amplification method involving primers. A plasmid containing EBV is disclosed as being amplified, which evidences the presence of a nucleic acid encoding EBV peptide, wherein such nucleic acid would necessarily have at least one nucleotide in common with SEQ ID NO: 1 or SEQ ID NO: 3.

Therefore, Ambinder et al. anticipate the invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ambinder et al. (Abstracts from Annual Meeting American Society of Microbiology, 1989, 89 Meet., 111, cited previously).

The teachings of Ambinder et al. have already been discussed above.

Ambinder et al. do not explicitly teach that the primers and reagents employed in their amplification reaction should be packaged into a kit.

It would have been *prima facie* obvious to one of ordinary skill in the art to package the reagent compositions of Ambinder into a kit in view of the conventionality of kits in the analytical arts for the advantages of convenience, cost-effectiveness, matched and/or preweighed components, etc.

Therefore, the invention as claimed is obvious over the cited references.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge

of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Young J. Kim
Patent Examiner
Art Unit 1637
12/22/04

YOUNG J. KIM
PATENT EXAMINER

yjk